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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,552	08/30/2001	Koji Kishi		9691
7590	11/12/2003		EXAMINER	
Luke A Kilyk Kilyk & Bowersox 53 A Lee Street Warrenton, VA 20186			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,552	Applicant(s) Kishi et al.
	Examiner Ralph Gitomer	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Sep 11, 2003
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 27-49 is/are pending in the application.
- 4a) Of the above, claim(s) 27-48 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

The amendments received 8/25/2003 and 9/11/2003 have been entered. It is noted this application claims priority to a PCT application but this application is not filed under 371 as a
5 National Stage application. Therefor, US restriction practice applies to this application. Claims 1 and 49 are considered here. It is noted the amendments to claim 1 are incompatible in the two amendments submitted, the version presented in the most recent 9/11/03 amendment will be considered here.

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Newly submitted claims 27-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The kit claims are directed to a separate and distinct invention from the method claims.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-48 are withdrawn from consideration as being directed to a non-elected invention. See
20 37 CFR 1.142(b) and MPEP § 821.03.

25

The presently claimed invention is directed to combinations of assaying for cholesterol fractions by controlling the reactivity of an enzyme by changing the ionic strength, a surfactant, or using an enzyme specific to the fraction. Each of 5 these methods is old for this function.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless -

15 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

20 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Nakamura, Miki (102(a)) and Sugiuchi.

25 Nakamura (6,057,118) entitled ~~Method for Quantitatively Determining LDL Cholesterol~~ teaches in the claims, determining LDL with a surfactant, a polyanion, with cholesterol esterase and cholesterol oxidase.

30 Miki (5,925,534) entitled ~~Method for Measuring LDL Cholesterol~~ teaches in the claims, determining LDL with a surfactant and a polyanion.

Sugiuchi (Clinical Chemistry) entitled ~~Homogeneous Assay~~ For Measuring Low Density Lipoprotein Cholesterol in Serum with Triblock Copolymer and Cyclodextrin Sulfate ~~teaches~~ in the abstract, determining LDL with POE-POP surfactant changes 5 reactivity of lipoprotein fractions. Cyclodextrin selectively reduced reactivity of cholesterol for determining LDL.

Each of the features of the claims are taught by each of the above references for the same function as claimed. Regarding new 10 claim 49 which includes a first and second surfactant, the surfactants may or may not be identical surfactants which is encompassed by the above references. Regarding an ion strength increasing compound, the concentration of water present would influence ionic strength as well as adding any ion.

15 Claims 1 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Yamauchi and Kerscher.

Yamauchi (Rinsho Kagaku) entitled ~~Evaluation of Reactivity~~ Using Direct Assay Methods for High Density Lipoprotein Cholesterol ~~teaches~~ in the abstract, determining HDL with PEG 20 modified enzymes or a polyanion and surfactant as compared to a precipitation method.

Kerscher (4,892,815) entitled ~~Process and Reagent for the Specific Determination of the Cholesterol of the HDL Fraction~~ ~~teaches~~ in column 2 lines 38-45, detergents and enzymes to 25 determine HDL. See the claims.

Each of the features of the claims are taught by each of the above references for the same function as claimed.

The amendments are silent concerning the above rejections to method claims.

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Claims 1 and 49 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all 10 occurrences.

In claim 1, ~~reacting the cholesterol~~ is queried. In claim 1, ~~the high-density lipoprotein~~ lacks antecedent basis. It is not seen how reactions are enabled. ~~Enabling an enzymatic reaction preferentially with respect to an object component~~ is not understood in context. There are no steps to accomplish the preamble directed to assaying a specific component. The method steps presented are introducing which is not seen to assay. Standard method steps may including contacting, determining, reacting and correlating. In claim 49 the two surfactants are not characterized in being the same or different which is confusing.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to 25 which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Gedik, Nursal, entitled ~~Direct Measurement of HDL Cholesterol in Serum with Polyethylene Glycol Modified Enzymes Cholesterol~~

5 Esterase and Cholesterol Oxidase~~■~~, Biyokim Derg 1998, 23(1)10-17 teaches measuring HDL cholesterol with modified enzymes that show selective catalytic activities in the presence of Mg+2.

10 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire 20 on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 872-9306. Any inquiry of a general nature or relating to the status

10 of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button **Patent Electronic Business Center** for more information.

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R. Gitomer
Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1651